

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY	)	MDL No.1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	Civil Action No. 01-CV-12257-PBS
	)	
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO:	)	
ALL CLASS ACTIONS	)	<b>FILED UNDER SEAL</b>
	)	<b>REDACTED VERSION</b>

**WATSON PHARMACEUTICALS, INC.'S INDIVIDUAL MEMORANDUM**  
**IN OPPOSITION TO CLASS CERTIFICATION**

Defendant Watson Pharmaceuticals, Inc. ("Watson") joins the Track Two Defendants' Memorandum in Opposition to Class Certification. For the additional reasons set forth in this Memorandum, none of the Plaintiffs' proposed classes should be certified as to Watson.

As explained in more detail below, Watson and its affiliates did not manufacture or distribute any generic drugs on which Plaintiffs base claims for proposed class representatives. Moreover, data provided to the Court by Plaintiffs show that only the proposed Class 2 representative may have paid any portion of a Medicare copayment on two brand-name subject drugs sold by Watson or one of its affiliates. According to documents filed with the Court by Plaintiffs, any copayments for one of these drugs, administered to a patient after January 1, 2005, were not based on AWP, and the administrations are outside of the proposed class period. The administrations of the other drug, iron dextran, do not meet the proposed class definition and are not representative of Plaintiffs' claims. Moreover, reimbursement records do not specify whether the patient received Watson's iron dextran or its competitor's, so certification of this class would require detailed, painstaking transaction-by-transaction analysis to determine

whether the drug was distributed by Watson or by its competitor. Class certification is therefore not warranted as to Watson.

### **Procedural Background**

In its Order dated August 16, 2005, relating to class certification for Track 1, the Court held, correctly, that “[p]laintiffs must establish that there is an individual class representative with standing to sue each defendant.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 80 (D. Mass. 2005). The Court also ruled that, in order to establish standing, Plaintiffs must “disclose the documents demonstrating that the proposed class representatives made co-insurance payments (at least in part) under Medicare Part B based on AWP.” *Id.* at 81. In its Order filed January 30, 2006, the Court further ruled that it would not certify a subclass among the individual Part B Co-Payment Class for Schering-Plough Corporation and Warrick Pharmaceuticals Corporation because “plaintiffs have not proposed any adequate and typical representatives of that proposed subclass,” since no proposed class representatives made a Part B copayment for Schering/Warrick drugs. Consolidated Order Re: Motion for Class Certification, at 3.

In their Motion to Certify Claims with Respect to Track 2 Defendants, Plaintiffs propose Joyce Howe and the Estate of Robert Howe and Roger Clark and the Estate of David Clark as Class 1 Representatives for Watson; Sheet Metal Workers National Fund (“Sheet Metal Workers”) as the Class 2 Representative for Watson; and Pipefitters Local 537 Trust Funds (“Pipefitters”) as the Class 3 Representative for Watson. Plaintiffs state that the “showing for each” individual class representative is set forth in the Declaration of Donald E. Haviland, Jr. (“Haviland Decl.”), for Sheet Metal Workers in the Affidavit of Glenn Randle (“Randle Aff.”), and for Pipefitters in the Declaration of Charles Hannaford (“Hannaford Decl.”).

**Argument**

**I. None of the Proposed Class Representatives Paid for a Watson Generic Drug.**

Plaintiffs must show by a preponderance of the evidence that proposed class representatives have standing. *Lee v. City of Chicago*, 330 F.3d 456, 468 (7th Cir. 2003); *Prado – Steiman v. Bush*, 221 F.3d 1266, 1279-80 (11th Cir. 2000). In fact, Watson can show by more than a preponderance of the evidence that the proposed class representatives do not have standing, because none of the proposed representatives paid even a portion of the Medicare copay on any generic drugs distributed or manufactured by Watson.

**a. Individual Class Representatives**

Plaintiffs state in their memorandum of law that Joyce and Robert Howe “paid for a drug manufactured by . . . Watson,” and that “Mr. [David] Clark paid for drugs manufactured by . . . Watson.” Mem. of Law in Supp. of Mot. to Certify Claims with Respect to Track 2 Defs., at 2-3. Both statements are untrue.

Records attached to the Haviland Declaration (and other documents provided in discovery) provide no information about which company manufactured or distributed the generic [REDACTED] which Mr. Howe received on [REDACTED] and [REDACTED]. That was the only drug for Mr. Howe within the class period that Plaintiffs assert might have been tied to Watson,<sup>1</sup> although the Haviland Declaration concedes multiple companies sold this drug. In fact, Watson did not even sell the strength of [REDACTED] that appears to have

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<sup>1</sup> The records attached to the Haviland Declaration also describe an administration of [REDACTED] on [REDACTED]. This administration is outside the class period. In addition, because of the date, reimbursement would not have been made based on AWP.

been administered to Mr. Howe.<sup>2</sup> Declaration of Jeffrey L. Johnson (“Johnson Decl.”) ¶¶ 11, 13 (attached as Ex. 1). Mr. Johnson also examined a chart of administrations distilled from records provided in discovery for Mr. Howe that were not discussed in the Haviland Declaration.

*Id.* ¶ 15; Declaration of Brian J. Wesoloski & Ex. A (attached as Ex. 2). The chart (and underlying records) show administrations of generic drugs that Plaintiffs attributed to Watson only on occasions when Watson’s sales were dwarfed by competitors’ sales. Johnson Decl. ¶ 15.

Similar analysis shows that it is nearly impossible that the [REDACTED] administered to Mr. Clark on [REDACTED] was manufactured or distributed by Watson or one of its affiliates. The Haviland Declaration states that the drug prescribed for Mr. Clark was manufactured by “Baxter, Fujisawa, the Sicor Group and Watson” but provides no evidence of which company sold the drug administered to Mr. Clark. Haviland Decl. ¶ 23. According to IMS data of [REDACTED] for Watson and its affiliates and the competitors in the market during [REDACTED] and [REDACTED], the Watson product amounted to less than one one-hundredth of one percent and less than three one-hundredths of one percent of the combined estimated sales (in extended units) of other sellers of the drug, respectively. Johnson Decl. ¶ 16. Again, the Johnson Declaration establishes that other generic drugs included in discovery records were not Watson drugs. *Id.* ¶ 17.

Accordingly, Plaintiffs have not met their burden of establishing by a preponderance of the evidence that the individual class representatives proposed for Watson have standing. On the contrary, Watson has established to a virtual certainty that the class representatives lack standing because the drugs that were administered to them were not Watson drugs.

<sup>2</sup> Even, assuming arguendo, that the notation of strength on the medical records was wrong (of which there is no evidence), according to reliable records generated by IMS Health, Inc. (“IMS”), Watson distributed either none or so little of the [REDACTED]

**b. Class 2 Representative**

More accurate than Plaintiffs' other filings, the Randle Affidavit states that the Sheet Metal Workers made payments for multi-source drugs that "may have been manufactured and sold" by companies including Watson. Randle Aff. ¶ 6 (emphasis supplied). Exhaustive review of the enormous database of records provided by the Sheet Metal Workers produced evidence of reimbursements for some of the drug products that Plaintiffs attributed to Watson (Randle Aff. Ex. 2), and a chart was created showing the dates of administration of the relevant drugs. Declaration of Michelle L. Butler & Ex. B ("Butler Decl.") (attached as Ex. 3). Applying the same analysis described above (using IMS data for the quarters in which the drug was administered and the prior quarter), Watson has conclusively established that it is highly unlikely or virtually impossible that any of the generic drugs listed were manufactured or distributed by Watson or any of its affiliates. Johnson Decl. ¶ 26.<sup>3</sup>

Accordingly, Sheet Metal Workers does not have standing as to Watson.

**c. Class 3 Representative**

The Pipefitters' data were also carefully analyzed to note any expenditures related to any of the drugs for which class status is sought for Watson. Butler Decl. Ex. A. As with the

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<sup>3</sup> [REDACTED] at the time that it is virtually impossible that the drug received by Mr. Howe was distributed by Watson or one of its affiliates. Johnson Decl. ¶¶ 12, 14. It should be noted that Mr. Randle listed on the table attached as Exhibit 2 to the Randle Affidavit two J-Codes for dexamethasone sodium phosphate (J7637 and J7638) that are actually codes for the inhalation form of the drug, whereas only the injectable form of the drug was listed as an AWPID in Appendix A to the Fourth Amended Master Consolidated Class Action Complaint ("FAMCC"). Watson has never distributed an inhalation form of the product. Butler Decl. ¶ 12. Moreover, the records attached to the Randle Affidavit as well as the other records produced by the Sheet Metal Workers do not show any administrations of dexamethasone sodium phosphate under J7637 or J7638. *Id.* ¶ 7. Finally, references to dexamethasone acetate being administered in 2004 were most likely a result of miscoding or the use of a compounded drug not attributable to Watson, since there were no injectable dexamethasone acetate products that were approved to be distributed by any manufacturer by the U.S. Food and Drug Administration after 2002. *Id.* ¶ 11.

proposed individual and Class 2 representatives, the administrations on which Plaintiffs attempt to base certification of Pipefitters as a class representative pertain to multi-source drugs for which Plaintiffs provided no documentation regarding which manufacturer actually provided the drug that was administered and reimbursed. IMS data were reviewed for the relevant periods, and, again, it was demonstrated that Watson and its affiliates were responsible for none or for a very small percentage of sales of the particular drugs involved. Johnson Decl. ¶¶ 18-22.<sup>4</sup>

Accordingly, it is very unlikely that Watson or its affiliates distributed or manufactured any of the generic drugs identified by Plaintiffs to support standing for their proposed class representatives. Plaintiffs have not met their burden of establishing, even under a relaxed standard of preponderance of the evidence, that their proposed class representatives paid any portion of the cost of a Watson drug.

## **II. Transactions Relating to Watson Brand Drugs Do Not Support Standing for the Proposed Class Representatives.**

Similarly, sparse evidence of payments by only one of the proposed class representatives for drugs that may have been Watson's branded drugs does not support standing. The only data provided by Plaintiffs for drugs that may have been Watson branded drugs are for iron dextran or sodium ferric gluconate. These transactions appear in the data relating to the Sheet Metal Workers, the proposed Class 2 representative. Transactions cited to the Court relating to Ferrlecit®, the brand name for sodium ferric gluconate, occurred on January 13 and January 20, 2005. As the Court is aware, Medicare reimbursements after January 1, 2005, were not based on AWP, and, therefore, those transactions do not support standing for Sheet Metal Workers as to

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<sup>4</sup> Curiously, Mr. Hannaford even transposed the names of the drugs in Exhibit 1 to his Declaration, since Exhibit 1 provides the J-Code for dexamethasone sodium phosphate but identifies the drug name as dexamethasone acetate, while the spreadsheet of data produced on behalf of the Pipefitters references dexamethasone sodium phosphate.

Watson. Moreover, any payment for any portion of the cost of sodium ferric gluconate would have occurred after the close of the proposed class period.

The data potentially relating to INFED® (Watson's brand name for iron dextran) are also flawed. The only payments for iron dextran injection presented to the Court are for a patient at the Welborn Clinic in Indiana over two months in 2002. *See* SMWMASS 001265-1267 (attached to Randle Aff. Ex. 3(n)). As an initial matter, the iron dextran administrations put forth by the Sheet Metal Workers do not satisfy the proposed Class 2 definition. The proposed definition is limited to third party payors that made reimbursements for drugs "purchased in Massachusetts."<sup>5</sup> Because the documentation regarding iron dextran demonstrates that the drugs were administered from outside of Massachusetts, these encounters do not satisfy the class definition, and thus cannot serve as the basis to certify a class against Watson. Additionally, Plaintiffs do not provide any documentation of actual payment or reimbursement by the Sheet Metal Workers for the iron dextran.

Moreover, in 2002, a competitive iron dextran product, Dexferrum, marketed by American Regent Laboratories, Inc., was available as well. Butler Decl. ¶¶ 13-14. Plaintiffs do not present any evidence to identify which manufacturer's product was administered to the patient. Furthermore, if the drug administered to the patient was Watson's drug, it would prove that the provider had not purchased based on the spread between the acquisition price and AWP because the margin on the competitive iron dextran product was greater than that on Watson's product. Dep. of Timothy Callahan, at 513-14 (Nov. 29, 2005). Accordingly, this proposed class representative would not be representative of Plaintiffs' claims that medical providers would choose the drug that provided the largest spread.

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<sup>5</sup> Sheet Metal Workers does not satisfy the alternative definition of having a principal place of business in Massachusetts. *See* FAMCC ¶ 30 (Fund office in Goodlettsville, TN).

Finally, the J-Code provided for these transactions was shared by Dexferrum and INFED through December 31, 2005. Most reimbursement records include only a J-Code, as evidenced by Plaintiffs' discovery in this matter. Butler Decl. ¶ 15. Approving a class relating to this drug would require exhaustive, transaction-by-transaction inquiry into the medical records of each patient who received iron dextran to determine which company's product was actually administered, which may be impossible, and certainly would be extremely difficult and time-consuming.

Therefore, Plaintiffs fail to establish, even by a preponderance of the evidence, that any proposed class representatives ever paid any portion of a Medicare copay for a Watson drug.

#### Conclusion

Plaintiffs have failed to establish standing for any of the class representatives proposed as to Watson, so no class should be certified as to Watson. Moreover, should the Court determine that the evidence proffered by Plaintiff as to brand drugs is sufficient, issues presented for generic drugs, and proof required to establish the links to a particular manufacturer, are so entirely different, a class should be certified only as to the brand drugs, and only as to Class 2.

Respectfully submitted,

*Douglas B. Farquhar* /MAB

Douglas B. Farquhar  
Michelle L. Butler  
Brian J. Wesoloski  
Hyman, Phelps & McNamara, P.C.  
700 13<sup>th</sup> Street, N.W., Suite 1200  
Washington, D.C. 20005  
(202) 737-5600  
(202) 737-9329 (Fax)



**CERTIFICATE OF SERVICE**

I hereby certify that I, Douglas B. Farquhar, caused a true and correct copy of the foregoing **WATSON PHARMACEUTICALS, INC.'S INDIVIDUAL MEMORANDUM IN OPPOSITION TO CLASS CERTIFICATION** and attached declarations and exhibits to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on June 15, 2006, a copy to LexisNexis File and Serve for posting and notification to all parties.

By /s/ Douglas B. Farquhar  
Douglas B. Farquhar  
Hyman, Phelps & McNamara, P.C.  
700 13<sup>th</sup> Street, N.W., Suite 1200  
Washington, D.C. 20005  
(202) 737-5600  
(202) 737-9329 (Fax)

# EXHIBIT 1

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY	)	MDL NO. 1456
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LITIGATION	)	CIVIL ACTION: 01-CV-12257-PBS
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**DECLARATION OF JEFFREY L. JOHNSON**

1. I am the Manager of Market Research with Watson Pharmaceuticals, Inc. (hereafter referred to as "Watson"). As part of my responsibilities in that job, I acquire and analyze data from IMS Health, Inc. (hereafter referred to as "IMS"). My educational background and job experience are set forth in Attachment A to this Declaration. The opinions set forth in this Declaration are expressed to a reasonable degree of professional certainty, unless otherwise stated.

2. Prior to being promoted to the Manager of Market Research in July 2003, I worked for about a year as a Senior Market Research Analyst at Watson. Before that, I worked for about a year as a Market Research Analyst at Watson. Prior to joining Watson, I worked as a Business Analyst for Mova Laboratories Inc. for about a year. In each of these positions, part of my job responsibilities included obtaining and analyzing data about prescription drug sales from IMS.

3. IMS is a company that, among other things, collects data about sales of pharmaceutical products, especially prescription drugs, and provides that data, for a fee, along with estimates of unit volume and sales by distributor for a particular type of drug. The data are collected from wholesalers, hospitals, HMOs (Health Maintenance Organizations), and chain drug stores, among other sources. IMS describes itself as “the one global source for pharmaceutical market intelligence, providing critical information, analysis and services that drive decisions and shape strategies,” and adds that “just about every major pharmaceutical and biotech company in the world is a customer of IMS.” Based on my experience and contact with employees of other pharmaceutical manufacturers and distributors, I believe these descriptions are correct.

4. I have been asked to review data from IMS for five drugs during portions of the period 1992 through 2005. The drugs are injectable dexamethasone acetate, injectable dexamethasone sodium phosphate, injectable gentamicin sulfate, injectable vancomycin hydrochloride, and diazepam intravenous solution. Neither Watson nor any of its affiliates has held an approved New Drug Application (“NDA”) for any of these drugs. Rather, they were marketed by Watson, or by one of its affiliates, at some time in the relevant period, as a generic drug, subject to an Abbreviated New Drug Application. I reviewed the IMS data to determine estimates of volume of sales of each drug for Watson (or its affiliates), compared with estimates of volumes of sales for the same drug for Watson’s competitors, during the relevant time period.

5. IMS data is collected as follows: IMS contracts with certain chain drug stores, Health Maintenance Organizations, hospitals, and drug wholesalers to purchase

evidence from each provider about its sales or use of particular drugs by manufacturer or distributor. Once the data have been gathered, IMS, using proprietary software, prepares a forecast estimating total sales of a particular drug in the United States sorted by manufacturer/distributor, class of trade, and many other factors.

6. While IMS data is generally reliable, and are relied upon in the pharmaceutical industry, to determine approximations of sales volume, the data are not trustworthy down to a fine level of detail, especially with generic, or multisource drugs. This is because, when a generic drug is dispensed at the retail pharmacy level or in a hospital or clinic, the pharmacist or pharmacy technician may miscode a particular NDC number (National Drug Code number, the unique identifier for each product for each company) for the drug, or forget to change the setting from a previous prescription, that would identify the manufacturer/distributor of a particular drug. Pharmacists and pharmacy technicians tend to focus, when recording data about individual prescriptions, on critical information to ensure that a patient is getting the prescribed dose of the appropriate strength of the appropriate medicine. The particular distributor or manufacturer of a generic drug is not relevant to those considerations. Accordingly, IMS data may show, for example, that a particular distributor's drug had a very small market share when that distributor was no longer distributing that product, and a pharmacist actually distributed another distributor's product. It is also possible that drugs with different but closely related chemical names (such as dexamethasone acetate and dexamethasone sodium phosphate), may be confused when a particular transaction is being recorded. Because IMS collects such data from a sample of the industry, and then

projects the data to estimate sales volume nationwide, an error on one or two transactions may result in a projection that would show errors in hundreds or even thousands of sales nationwide.

7. IMS data is sorted to project sales volume for a particular distributor, rather than a particular manufacturer, because it is the company listed on the label, rather than the company that holds the FDA approval to manufacture the drug, that will be recorded by the dispensing pharmacist. In other words, if a given drug is manufactured by Company A under contract with Company B, Company B's name would appear on the label, the NDC number for the drug would belong to Company B, and, in all likelihood, IMS data should be recorded for Company B.

8. To determine the likelihood that a given drug administered to a particular patient on a specific date came from a particular distributor, the IMS data for Extended Units, or "EU," are more reliable than the data on dollar volume of a particular drug. This is because the likelihood that the drug came from a particular company would be independent of the cost of that drug. In other words, if we assumed that two companies each sold half of the units of a particular drug, but Company A charged three times as much as Company B for the drug, in the absence of other data, there would be a 50 percent chance that the drug given on a particular occasion was sold by Company A (the estimate based on unit volume) rather than a 75 percent probability (the estimate that would have been based on dollar volume). Therefore, in analyzing market data on the relevant drugs, at the relevant times, I reviewed data on Extended Units. With regard to these drugs, an Extended Unit is a milliliter of the drug.

9. To determine the likelihood that a particular drug administered to a particular patient on a particular date was distributed by Watson or one of its affiliates, I reviewed data on estimated sales volume in the quarter when the drug was administered, and in the quarter before the quarter in which the drug was administered. These were the most appropriate periods to review because high-volume injectable generic drugs are generally not stocked by hospitals, clinics, or physicians' offices months in advance, and it is quite likely that a drug administered to a patient would have been purchased by the health care provider within a couple of months before the drug was administered.

10. IMS data demonstrate that it is extremely unlikely, bordering on impossible, that Watson or any of its affiliates distributed the above-cited drugs that were administered to the class representatives or the patients they represent and described in the Declaration of Donald E. Haviland, Jr., or its attachments, for proposed class representatives Joyce Howe, the Estate of Robert Howe, Roger Clark, and the Estate of David Clark. Specifically, the Declaration and the attached medical records show the following drugs administered on the following dates.

11. [REDACTED] (misspelled in Mr. Haviland's Declaration and in the medical records as [REDACTED] was administered, according to the medical records, to Robert Howe on [REDACTED] with a charge from the health care provider of [REDACTED]. IMS data show that, [REDACTED], Watson and its affiliates did not distribute any [REDACTED], that one company (or one of its affiliates) distributed an estimated [REDACTED] Extended Units of [REDACTED] [REDACTED] that a second company (or one of its affiliates) distributed an estimated [REDACTED]

Extended Units of the [REDACTED] that the first company (or one of its affiliates) distributed an estimated [REDACTED] Extended Units of the [REDACTED] [REDACTED] and that several other manufacturers or distributors distributed less than [REDACTED] Extended Units of [REDACTED]. Likewise, [REDACTED] IMS data show that Watson and its affiliates did not distribute any [REDACTED] that one company (or one of its affiliates) distributed an estimated [REDACTED] Extended Units of [REDACTED] that a second company (or one of its affiliates) distributed an estimated [REDACTED] Extended Units of the [REDACTED], that the first company (or one of its affiliates) distributed an estimated [REDACTED] Extended Units of the [REDACTED] [REDACTED] and that several other manufacturers or distributors distributed less than [REDACTED] Extended Units of [REDACTED]. Furthermore, I have checked the records of Watson and its affiliates, and it appears that Watson and its affiliated companies never distributed any [REDACTED]. Accordingly, it is my opinion, to near certainty, that any [REDACTED] administered to Robert Howe on [REDACTED] was not manufactured or distributed by Watson or any of its affiliates.

12. Even if Mr. Howe actually received two doses of [REDACTED] [REDACTED] (a product that Watson did distribute for a time), it is extremely unlikely that the drug was manufactured or distributed by Watson or one of its affiliates. The chart below shows IMS estimates of sales volume (in Extended Units) for the quarter that includes [REDACTED] and the prior quarter.



Drug name: [REDACTED]

Date of administration: [REDACTED]

Relevant quarters: [REDACTED]

<b>Distributors:</b>	[REDACTED]	[REDACTED]
Single Largest Distributor	[REDACTED]	[REDACTED]
Watson Pharmaceutical <sup>1</sup>	[REDACTED]	[REDACTED]
Steris Laboratories <sup>1</sup>	[REDACTED]	[REDACTED]

Thus, it is very unlikely, bordering on the impossible, that Mr. Howe received [REDACTED] distributed by Watson or one of its affiliates.

13. [REDACTED] was also administered, according to the medical records, to Robert Howe on [REDACTED] with a charge from the health care provider of [REDACTED]. IMS data show that, [REDACTED], Watson and its affiliates did not distribute any [REDACTED] that one company (or one of its affiliates) distributed an estimated [REDACTED] Extended Units of [REDACTED], that a second company (or one of its affiliates) distributed an estimated [REDACTED] Extended Units of the [REDACTED], that the first company (or one of its affiliates) distributed an estimated [REDACTED] Extended Units of the [REDACTED], and that several other manufacturers or distributors distributed less than [REDACTED] Extended Units of [REDACTED]. Likewise, [REDACTED]. IMS data show that Watson and its affiliates did not distribute any [REDACTED] that one company (or one of its affiliates) distributed an

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<sup>1</sup> Steris was acquired by Schein Pharmaceuticals, Inc., which was later acquired by Watson.

estimated [REDACTED] Extended Units of [REDACTED] that a second company (or one of its affiliates) distributed an estimated [REDACTED] Extended Units of the [REDACTED] that the first company (or one of its affiliates) distributed an estimated [REDACTED] Extended Units of the [REDACTED] [REDACTED] and that several other manufacturers or distributors distributed less than [REDACTED] Extended Units of [REDACTED]. As discussed above, I have checked the records of Watson and its affiliates, and it appears that Watson and its affiliated companies never distributed any [REDACTED]. Accordingly, it is my opinion, to near certainty, that any [REDACTED] administered to Robert Howe on [REDACTED] was not manufactured or distributed by Watson or any of its affiliates.

14. Even if Mr. Howe actually received two doses of [REDACTED] (a product that Watson did distribute for a time), it is extremely unlikely that the drug was manufactured or distributed by Watson or one of its affiliates. The chart below shows IMS estimates of sales volume (in Extended Units) for the quarter that includes [REDACTED] and the prior quarter.

**Drug name:** [REDACTED]  
**Date of administration:** [REDACTED]  
**Relevant quarters:** [REDACTED]

<b>Distributors:</b>	[REDACTED]	[REDACTED]
Single Largest Distributor	[REDACTED]	[REDACTED]
Watson Pharmaceutical	[REDACTED]	[REDACTED]
Steris Laboratories	[REDACTED]	[REDACTED]

Thus, it is very unlikely, bordering on the impossible, that Mr. Howe received [REDACTED]

[REDACTED] distributed by Watson or one of its affiliates.

15. I have reviewed a chart prepared for Robert Howe, which shows any other administrations listed in data provided by the Plaintiffs for any generic injectable drugs that are subject drugs for Watson in the Fourth Amended Master Consolidated Class Action Complaint (Exhibit A to the Declaration of Brian J. Wesoloski), and then reviewed the IMS and Watson records to determine if there is any possibility that the drugs administered to Mr. Howe were manufactured or distributed by Watson or any of its affiliates. During the quarters surrounding any administrations of these drugs, Watson either distributed none or a miniscule percentage of the drugs involved.

16. According to the Haviland Declaration, David E. Clark received an [REDACTED] on [REDACTED] for which there was a charge of [REDACTED]. The entry on the bill is misspelled as "[REDACTED]" but the "Service Code" provided by the [REDACTED] is the Medicare J-Code for an [REDACTED]. [REDACTED] IMS data show that, [REDACTED], Watson and its affiliates distributed no [REDACTED] or virtually none, while several other companies distributed more than [REDACTED] Extended Units of the drug each quarter. Specifically, the IMS data for the relevant quarters are summarized in the chart below which sets forth the estimated number of sales, based on Extended Units as reported by IMS, for the distributors during the relevant quarters.

Drug name: [REDACTED]

Date of administration: [REDACTED]

Relevant quarters: [REDACTED]

<b>Name of distributor:</b>	[REDACTED]	[REDACTED]
Four Largest Distributors	[REDACTED]	[REDACTED]
Watson Pharmaceuticals	[REDACTED]	[REDACTED]
Steris Laboratories	[REDACTED]	[REDACTED]

It is actually likely a mistake that Steris is listed as having any sales, since the Steris injectable manufacturing facility was closed down under a Consent Decree with the federal government in late 1998. No other sales of [REDACTED] are shown for any other Watson affiliate. Therefore, even if the sales for Steris products are accurate, it is extremely unlikely that the [REDACTED] administered to Mr. Clark was manufactured or distributed by Watson or any of its affiliates. The estimated sales of Steris products amount to less than one one-hundredth of one percent in the [REDACTED] and less than three one-hundredths of one percent in the [REDACTED] of the sales of the four largest distributors of that drug.

17. I have reviewed a chart prepared for Mr. Clark, which shows any other administrations listed in medical and reimbursement records provided by the Plaintiffs for any generic injectable drugs that are subject drugs for Watson in the Fourth Amended Master Consolidated Class Action Complaint (Exhibit A to the Declaration of Brian J. Wesoloski), and then reviewed the IMS and Watson records to determine if there is any possibility that the drugs were manufactured or distributed by Watson or any of its affiliates. During the quarters surrounding any administrations of these drugs, Watson either distributed none or a miniscule percentage of the drugs involved.

18. I engaged in the same analysis of the generic drugs that Watson may have distributed and that were reimbursed by either the Pipefitters Local 537 Trust Funds (“Pipefitters”) or the Sheet Metal Workers National Health Fund (“Sheet Metal Workers”). I have come to the conclusion that all of the generic drugs listed in those records also are extremely unlikely to have been manufactured or distributed by Watson or any of its affiliates, according to the IMS data.

19. I have reviewed a chart prepared for the Pipefitters, which shows any other administrations listed in the spreadsheet of data provided by the Plaintiffs for any generic injectable drugs that are subject drugs for Watson in the Fourth Amended Master Consolidated Class Action Complaint (Exhibit A to the Declaration of Michelle L. Butler). The Pipefitters data provided by Plaintiffs show the following reimbursements for generic injectable Watson drugs identified as subject drugs in this case: six administrations of dexamethasone sodium phosphate<sup>2</sup> occurring in April through May 2001, February 2004, and May 2005; one administration of diazepam in August 1999; and one administration of vancomycin hydrochloride in November 2002. Again, I can state that it is extremely unlikely that any of these drugs was manufactured or distributed by Watson. In the first and second quarters of 2001, Watson and its affiliates distributed a very small percentage of the dexamethasone sodium phosphate distributed in the United

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<sup>2</sup> Although the spreadsheet of data regarding the Pipefitters provided by the Plaintiffs identifies the drug administrations as dexamethasone sodium phosphate, Exhibit 1 (Pipefitters Local 537 Trust Fund Summary of Track 2 Drug Coverage) to the Declaration of Charles Hannaford provided the J-Code for dexamethasone sodium phosphate (J1100), yet identifies the drug name as dexamethasone acetate.

States, while several other companies distributed more than 10 million units of the drug, as shown by the IMS data summarized in the chart below (in Extended Units):

**Drug name:** Dexamethasone sodium phosphate  
**Dates of administration:** April through May 2001  
**Relevant quarters:** First and second quarters 2001

<b>Distributors:</b>	<b>1<sup>st</sup> Q 2001</b>	<b>2<sup>nd</sup> Q 2001</b>
Four Largest Distributors <sup>3</sup>	10,436,000	9,858,000
Watson Pharmaceuticals	35,000	13,000
Steris Laboratories	61,000	4,000

No other sales of dexamethasone sodium phosphate are shown for any other Watson affiliate. Therefore, it is extremely unlikely that the dexamethasone sodium phosphate administered during this period to any of the patients covered by Pipefitters was manufactured or distributed by Watson or any of its affiliates, since Watson and Steris distributed less than one percent of the dexamethasone sodium phosphate in the first quarter of 2001, and less than one quarter of one percent in the second quarter.

20. As to the administration of dexamethasone sodium phosphate in February 2004, the IMS data also show that it is very unlikely that Watson's drug was administered. The IMS data for the last quarter of 2003 and first quarter of 2004 are set forth in the chart below (in Extended Units):

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<sup>3</sup> According to the IMS data estimates, in the first quarter of 2001, one of these distributors sold less dexamethasone sodium phosphate than Watson and Steris (10,000 EU), but in the second quarter, it sold significantly more than Watson and Steris combined (154,000 EU).

**Drug name:** Dexamethasone sodium phosphate

**Date of administration:** February 2004

**Relevant quarters:** Last quarter of 2003 and first quarter of 2004

<b>Name of distributor:</b>	<b>4<sup>th</sup> Q 2003</b>	<b>1<sup>st</sup> Q 2004</b>
Four Largest Distributors	17,377,000	20,097,000
Watson Pharmaceuticals	None	1,000
Steris Laboratories	1,000	2,000

Again, it is likely that the Extended Units attributed to Watson and Steris are actually mistakes, due to coding errors, since the Steris injectable manufacturing facility was closed down under a Consent Decree with the federal government in late 1998, and we believe that Watson did not distribute any of this drug in either period. No other sales of dexamethasone sodium phosphate are shown for any other Watson affiliate. Therefore, it is extremely unlikely that the dexamethasone sodium phosphate administered in February 2004 was manufactured or distributed by Watson or any of its affiliates.

21. IMS data available for the administration of dexamethasone sodium phosphate during the period surrounding May 2005 also demonstrate the near impossibility that dexamethasone sodium phosphate administered in that month was Watson's drug, or was distributed by one of its affiliated entities. The IMS data (in Extended Units) for the relevant quarters show that other companies distributed all, or nearly all, of the drug:

**Drug name:** Dexamethasone sodium phosphate

**Date of administration:** May 2005

**Relevant quarters:** First and second quarters of 2005

<b>Distributors:</b>	<b>1<sup>st</sup> Q 2005</b>	<b>2<sup>nd</sup> Q 2005</b>
Four Largest Distributors	18,611,000	18,146,000
Watson Pharmaceuticals	None	None
Steris Laboratories	1,000	1,000

Again, the projected sales attributed to Steris are likely actually a mistake, due to a coding error, since the Steris injectable manufacturing facility was closed down under a Consent Decree with the federal government in late 1998. No other sales of dexamethasone sodium phosphate are shown for any other Watson affiliate. Therefore, it is extremely unlikely that the dexamethasone sodium phosphate administered in May 2005 was manufactured or distributed by Watson or any of its affiliates.

22. The following data are relevant to the administration of vancomycin hydrochloride in November 2002. In the third quarter of 2002, Watson and its affiliates distributed none of the injectable vancomycin hydrochloride distributed in the United States, while several other companies distributed more than 68,734,000 units of the drug. Likewise, in the fourth quarter of 2002, IMS data show that Watson and its affiliates distributed none of the injectable vancomycin hydrochloride distributed in the United States, while several other companies distributed nearly 71.9 million Extended Units of the drug. Therefore, it is virtually impossible that the vancomycin hydrochloride administered to the patient covered by Pipefitters was manufactured or distributed by Watson or any of its affiliates.

23. The following data are relevant to the administration of diazepam in August 1999. IMS data show that Watson's and Schein's estimated sales of diazepam were again dwarfed by sales of competitors' products, as indicated in the chart below:



**Drug name: Diazepam**

**Date of administration: August 1999**

**Relevant quarters: Second and third quarters of 1999**

<b>Distributors:</b>	<b>2<sup>nd</sup> Q 1999</b>	<b>3<sup>rd</sup> Q 1999</b>
Three Largest Distributors	1,989,000	2,013,000
Watson Pharmaceuticals	43,000	47,000
Steris Laboratories	50,000	16,000

Therefore, it is highly unlikely that the diazepam administered in August 1999 was manufactured or distributed by Watson or its affiliates.

24. The Affidavit of Glenn Randle lists, in Exhibit 2, the following drugs for which class representation is sought for the Sheet Metal Workers as to Watson: dexamethasone acetate, dexamethasone sodium phosphate, diazepam IV, Ferrlecit, gentamicin, INFeD, and vancomycin. Although INFeD (iron dextran) and Ferrlecit (sodium ferric gluconate) are listed in this Exhibit as multi-source drugs, both are brand-name products rather than generic drugs. Moreover, a second brand-name iron dextran product has been on the market since 1996 (and, until January 1, 2006, shared a J-Code with INFeD).

25. According to Exhibit B to the Declaration of Michelle L. Butler, the data submitted by Sheet Metal Workers show reimbursements for a portion of the costs of the following generic injectable drugs, administered in the following months:

Dexamethasone acetate: April and May 2004

Dexamethasone sodium phosphate: July through October 1998, August 2000, February 2001, April and May 2001, September through November 2001, March 2002, August 2002, February 2003, September 2003, January through June 2004, August and

September 2004, December 2004 through January 2005, March 2005

Diazepam IV: September 2002

Gentamicin sulfate: December 2001 and January 2004

Vancomycin hydrochloride: December 2001, September 2003, September 2005

26. Because the IMS data show almost no sales of dexamethasone acetate during the relevant quarters, it is my firm opinion that the drugs administered in April and May 2004 were either compounded drug product (which would not have been manufactured or distributed by Watson or any affiliate) or actually miscoded, and really dexamethasone sodium phosphate, a very similar molecular entity. Therefore, I set forth in the charts below the estimated sales volume (in Extended Units) from IMS data for each of the quarters for dexamethasone sodium phosphate, to the extent not already discussed.

**Drug name:** Dexamethasone sodium phosphate

**Date of administration:** July through October 1998, August 2000

**Relevant quarters:** Second and third quarter 1998, second and third quarter 2000

<b>Distributors:</b>	<b>2<sup>nd</sup> Q 1998</b>	<b>3<sup>rd</sup> Q 1998</b>	<b>2<sup>nd</sup> Q 2000</b>	<b>3<sup>rd</sup> Q 2000</b>
Four Largest Distributors	7,280,000	7,516,000	10,133,000	9,048,000
Steris	337,000	94,000	171,000	14,000
Watson	537,000	478,000	25,000	14,000

Therefore, Watson and Steris sales of dexamethasone sodium phosphate during the relevant period ranged from only about 12 percent to about 0.3 percent of the estimated sales of the four largest distributors, making it very unlikely that the drugs administered and reimbursed by Sheet Metal Workers were distributed by Watson or one of its affiliates. Similar data exist for all other administrations of dexamethasone sodium

phosphate, diazepam, gentamicin sulfate, and vancomycin hydrochloride as follows.<sup>4</sup>

**Drug name:** Dexamethasone sodium phosphate

**Date of administration:** February 2001, April and May 2001, September through November 2001, March 2002, August 2002, February 2003, September 2003, January through June 2004, August and September 2004, December 2004 through January 2005, March 2005

**Relevant quarters:** Fourth quarter 2000; first\*, second\*, third and fourth\* quarter 2001; first\*, second, third and fourth quarter 2002; first, second, third and fourth\* quarter 2003; first, second\*, third and fourth quarter 2004; first\* and second\* quarter 2005

<b>Distributors:</b>	<b>4<sup>th</sup> Q 1998</b>	<b>4<sup>th</sup> Q 2000</b>	<b>3<sup>rd</sup> Q 2001</b>	<b>2<sup>nd</sup> Q 2002</b>
Four Largest Distributors	9,049,000	8,948,000	11,054,000	12,707,000
Steris	88,000	19,000	3,000	2,000
Watson	96,000	5,000	26,000	None

<b>Distributors:</b>	<b>3<sup>rd</sup> Q 2002</b>	<b>4<sup>th</sup> Q 2002</b>	<b>1st Q 2003</b>	<b>2<sup>nd</sup> Q 2003</b>
Four Largest Distributors	14,154,000	15,463,000	24,365,000	19,530,000
Steris	3,000	1,000	8,000	None
Watson	None	None	5,000	None

<b>Distributors:</b>	<b>3<sup>rd</sup> Q 2003</b>	<b>2<sup>nd</sup> Q 2004</b>	<b>3<sup>rd</sup> Q 2004</b>	<b>4<sup>th</sup> Q 2004</b>
Four Largest Distributors	17,367,000	18,630,000	19,027,000	18,036,000
Steris	1,000	4,000	2,000	2,000
Watson	None	None	None	1,000

<sup>4</sup> See charts in paragraphs 14, 17, 18, and 23 for the data for quarters marked with an asterisk.

**Drug name:** Diazepam IV**Date of administration:** September 2002**Relevant Quarters:** Second and third quarter 2002

<b>Distributors:</b>	<b>2<sup>nd</sup> Q 2002</b>	<b>3<sup>rd</sup> Q 2002</b>
Four Largest Distributors <sup>5</sup>	1,470,000	2,679,000
Steris	2,000	7,000
Watson	None	None

**Drug name:** Gentamicin sulfate (not inclusive of NS formulation)**Date of administration:** December 2001 and January 2004**Relevant quarters:** Third and fourth quarter 2001, fourth quarter 2003, first quarter 2004

<b>Distributors:</b>	<b>3<sup>rd</sup> Q 2001</b>	<b>4<sup>th</sup> Q 2001</b>	<b>4<sup>th</sup> Q 2003</b>	<b>1<sup>st</sup> Q 2004</b>
Four Largest Distributors	26,719,000	33,915,000	23,196,000	22,179,000
Watson	None	None	None	None
Steris	None	None	None	None

**Drug name:** Vancomycin hydrochloride**Date of administration:** December 2001, September 2003, September 2005**Relevant quarters:** Third and fourth quarter 2001, second and third quarter 2003, second and third quarter 2005

<b>Distributors:</b>	<b>3<sup>rd</sup> Q 2001</b>	<b>4<sup>th</sup> Q 2001</b>	<b>2<sup>nd</sup> Q 2003</b>	<b>3<sup>rd</sup> Q 2003</b>
Three Largest Distributors	46,979,000	52,899,000	82,595,000	81,034,000
Watson	None	None	None	None

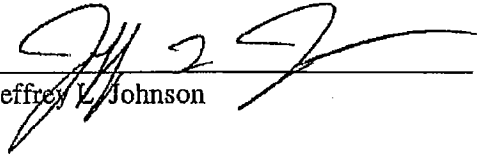
<b>Distributors:</b>	<b>2<sup>nd</sup> Q 2005</b>	<b>3<sup>rd</sup> Q 2005</b>
Three Largest Distributors	46,616,000	50,327,000
Watson	None	None

<sup>5</sup> One company had the lion's share of the estimated sales (1,450,000 EU in the second quarter of 2002 and 2,659,000 EU in the third quarter of 2002). Three other companies accounted for the remaining estimated sales (other than the projected Watson/Steris sales), each company with greater sales than Watson/Steris over the two quarters combined.

27. Therefore, it is my opinion, to a reasonable degree of professional certainty, that the IMS data demonstrate that it is unlikely that any of the generic drugs identified in the records for individual proposed class representatives or for entity class representatives were manufactured or distributed by Watson or any of its affiliates.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 15<sup>th</sup> day of June, 2006.

  
\_\_\_\_\_  
Jeffrey L. Johnson

# EXHIBIT 2

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY	)	MDL NO. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	CIVIL ACTION: 01-CV-12257-PBS
	)	
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO	)	
ALL CLASS ACTIONS	)	<b>FILED UNDER SEAL</b>
	)	<b>REDACTED VERSION</b>

**DECLARATION OF BRIAN J. WESOLOSKI**

1. I am an attorney at Hyman, Phelps & McNamara, P.C. I am one of the attorneys representing Watson Pharmaceuticals, Inc. ("Watson") in this litigation.

2. I reviewed the Declaration of Donald E. Haviland, Jr. ("Haviland Declaration"), the attached exhibit to the Haviland Declaration pertaining to Joyce Howe and the Estate of Robert Howe (Exhibit A to the Haviland Declaration), the attached exhibit to the Haviland Declaration pertaining to Roger Clark and the Estate of David Clark (Exhibit K to the Haviland Declaration), and medical and reimbursement records provided by the Plaintiffs for Robert Howe and David Clark for any drugs that are physician-administered, generic subject drugs for Watson listed in Appendix A to the Fourth Amended Master Consolidated Class Action Complaint. Those drugs are injectable dexamethasone acetate, injectable dexamethasone sodium phosphate, injectable gentamicin sulfate, injectable vancomycin hydrochloride, and diazepam intravenous solution ("Subject Drugs"). In addition, I reviewed the documents

referenced above for the branded drugs INFeD and Ferlecit.

3. I reviewed the above-referenced documents for both the names and the Medicare J-Codes of the Subject Drugs and the two branded drugs. Because the Haviland Declaration did not reference any J-Codes pertaining to the Subject Drugs, I relied on the list of relevant J-Codes contained in Exhibit 2 to the Affidavit of Glenn Randle ("Randle Affidavit") for the purposes of my review. Those J-Codes are as follows: J1094 (injectable dexamethasone acetate), J1100 (injectable dexamethasone sodium phosphate), J1580 (injectable gentamicin sulfate), J3370 (injectable vancomycin hydrochloride), J3360 (diazepam intravenous solution), J1750 (iron dextran, including INFeD), and J2916 (Ferlecit). Exhibit 2 to the Randle Affidavit also contains two J-Codes for dexamethasone sodium phosphate, namely, J7637, and J7638, that relate to inhalation products, not injectable products. I did not find any instances of administration of the J7637 or J7638 in any of the discovery materials referenced above.

4. A secretary acting under my direction prepared a chart showing the name of the relevant patient, the date of administration of the Subject Drug, the name of the Subject Drug of administration, and the J-Code of the Subject Drug. In addition, the secretary inserted an asterisk after the name of the patient for those administrations of a Subject Drug for which information was filed with the Court (i.e., discussed in the text of the Haviland Declaration or included in Exhibits A or K to the Haviland Declaration).

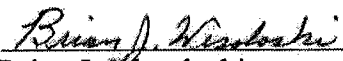
5. I reviewed the above-referenced chart and checked its accuracy against the information and data I provided to the above-referenced secretary. I corrected any errors on the chart (attached as "Exhibit A").



6. Exhibit A represents all of the drug administrations contained in all of the discovery materials relating to the Subject Drugs for the above-referenced proposed class representatives.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 15<sup>th</sup> day of June, 2006.

  
\_\_\_\_\_  
Brian J. Wesoloski

# EXHIBIT A

Proposed Class Representatives:  
 Joyce Howe and the Estate of Robert Howe  
 Roger Clark and the Estate of David Clark  
 (Class 1)

Name	Date of Administration	Date of Administration	Date of Administration
David Clark	[REDACTED]	[REDACTED]	[REDACTED]
David Clark*	[REDACTED]	[REDACTED]	[REDACTED]
David Clark	[REDACTED]	[REDACTED]	[REDACTED]
Robert Howe*	[REDACTED]	[REDACTED]	[REDACTED]
Robert Howe	[REDACTED]	[REDACTED]	[REDACTED]
Robert Howe	[REDACTED]	[REDACTED]	[REDACTED]
Robert Howe*	[REDACTED]	[REDACTED]	[REDACTED]
Robert Howe	[REDACTED]	[REDACTED]	[REDACTED]
Robert Howe	[REDACTED]	[REDACTED]	[REDACTED]
Robert Howe	[REDACTED]	[REDACTED]	[REDACTED]
Robert Howe*	[REDACTED]	[REDACTED]	[REDACTED]

\*Contained in Haviland Declaration

# EXHIBIT 3

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY	)	MDL NO. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	CIVIL ACTION: 01-CV-12257-PBS
	)	
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO	)	
ALL CLASS ACTIONS	)	<b>FILED UNDER SEAL</b>
	)	<b>REDACTED VERSION</b>

**DECLARATION OF MICHELLE L. BUTLER**

1. I am an attorney at Hyman, Phelps & McNamara, P.C. I am one of the attorneys representing Watson Pharmaceuticals, Inc. (“Watson”) in this litigation.

2. I reviewed the Declaration of Charles Hannaford (“Hannaford Declaration”), the attached exhibit to the Hannaford Declaration purporting to provide a summary of Track 2 drug coverage (Exhibit 1 to the Hannaford Declaration), and the data table produced by Plaintiffs on behalf of the Pipefitters Local 537 Trust Funds (“Pipefitters”) for any drugs that are physician-administered, generic subject drugs for Watson listed in Appendix A to the Fourth Amended Master Consolidated Class Action Complaint. Those drugs are injectable dexamethasone acetate, injectable dexamethasone sodium phosphate, injectable gentamicin sulfate, injectable vancomycin hydrochloride, and diazepam intravenous solution (“Subject Drugs”). I also reviewed the documents referenced above for the branded drugs, INFeD<sup>®</sup> and Ferrlecit<sup>®</sup>.

3. I reviewed the data table for the Medicare J-Codes listed in Exhibit 1 to the Hannaford Declaration as pertaining to Watson. Those J-Codes are as follows: J1100 (injectable dexamethasone sodium phosphate),<sup>1</sup> J3370 (injectable vancomycin hydrochloride), and J3360 (diazepam intravenous solution).

4. I prepared a chart showing the name of the relevant patient (if available), the date of administration of the Subject Drug, the name of the Subject Drug of administration, and the J-Code of the Subject Drug (attached as "Exhibit A").

5. Exhibit A represents all of the generic drug administrations contained in all of the discovery materials relating to the Subject Drugs for the Pipefitters.

6. Legal assistants under my direct supervision reviewed the Affidavit of Glenn Randle ("Randle Affidavit"), the attached exhibit to the Randle Affidavit purporting to provide a summary of Track 2 drug coverage (Exhibit 2 to the Randle Affidavit), the attached exhibit pertaining to Watson (Exhibit 3(n) to the Randle Affidavit), and medical and reimbursement records provided by the Plaintiffs on behalf of the Sheet Metal Workers National Health Fund ("Sheet Metal Workers") for the Subject Drugs. In addition, these legal assistants reviewed the documents referenced above for the branded drugs, INFED and Ferrlecit.

7. Legal assistants under my direction reviewed the above-referenced documents for the Medicare J-Codes of the Subject Drugs and the two branded drugs

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<sup>1</sup> Exhibit 1 to the Hannaford Declaration provides the J-Code for dexamethasone sodium phosphate but identifies the drug name as dexamethasone acetate, while the spreadsheet of data produced on behalf of the Pipefitters references dexamethasone sodium phosphate.

contained in Exhibit 2 to the Randle Affidavit. Those J-Codes are as follows: J1094 (injectable dexamethasone acetate), J1100 (injectable dexamethasone sodium phosphate), J1580 (injectable gentamicin sulfate), J3370 (injectable vancomycin hydrochloride), J3360 (diazepam intravenous solution), J1750 (iron dextran, including INFeD), and J2916 (Ferrlecit). Exhibit 2 to the Randle Affidavit also contains two J-Codes for dexamethasone sodium phosphate, namely, J7637, and J7638, that relate to inhalation products, not injectable products. Although J7637 and J7638 do not refer to Subject Drugs, the Sheet Metal Workers discovery materials were reviewed for those J-Codes and no instances of administration or reimbursement of drugs with those J-Codes were found.

8. Legal assistants acting under my direction prepared a chart showing the name of the relevant patient (if available), the date of administration of a Subject Drug, the name of the Subject Drug of administration, and the J-Code of the Subject Drug. In addition, an asterisk was placed in the column for the name of the patient for those administrations of a Subject Drug for which information was filed with the Court (i.e., included in Exhibit 3(n) to the Randle Affidavit).

9. I reviewed the above-referenced chart and checked its accuracy against the medical and reimbursement records. I corrected any errors on the chart (attached as "Exhibit B"). In my review of the medical and reimbursement records, I found that the vast majority of the records identified a drug only by J-Code. In some cases, the records

also supplied the generic name of the drug. On rare occasions, a record also contained an NDC number. None of the records that contained NDC numbers related to Watson Subject Drugs.

10. Exhibit B represents all of the drug administrations contained in all of the discovery materials relating to the J-Codes identified in the Randle Affidavit as pertaining to Subject Drugs for the Sheet Metal Workers.

11. Regarding dexamethasone acetate, I reviewed the Food and Drug Administration's ("FDA's") *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for 2002 and 2003. The 2002 Orange Book contains listings in the "Prescription Drug Product List" for dexamethasone acetate products. 2002 Orange Book at 3-105. In the 2003 Orange Book, there are no listings for any dexamethasone acetate products in the "Prescription Drug Product List." However, the products that were on the approved list in 2002 are located in the "Discontinued Drug Product List" in the 2003 Orange Book. 2003 Orange Book at 6-35.

12. Regarding the inhalation dexamethasone sodium phosphate products, I queried FDA's Electronic Orange Book, *available at* <http://www.fda.gov/cder/ob/default.htm>. When I searched by active ingredient for "dexamethasone" in the "RX (Prescription Drug Products)" list, I found no currently approved inhalation dexamethasone sodium phosphate products. Moreover, when I searched by active ingredient for "dexamethasone" in the "Disc (Discontinued Drug Products)" list, I found only two dexamethasone sodium phosphate inhalation products that had been approved and discontinued – a metered aerosol inhalation product and a



nasal aerosol product – neither of which was manufactured by Watson or any of its affiliates.

13. Regarding iron dextran, I queried FDA's Electronic Orange Book and found three approved iron dextran products:

- INFeD, approved prior to January 1, 1982, with the applicant identified as Watson Labs (Utah);
- Dexferrum, approved February 23, 1996, with the applicant identified as Luitpold; and
- Proferdex, approved prior to January 1, 1982, with the applicant noted as New River.

14. I searched the Internet via Google.com for Dexferrum and found that it is marketed in the United States by American Regent Laboratories, Inc., a Luitpold Pharmaceuticals, Inc. company. See <http://www.americanregent.com/home.html>.

15. I reviewed information from the Healthcare Common Procedure Coding System for 2000 through 2005. I found that each entry for INFeD and each entry for Dexferrum refers to the entry for iron dextran and its associated J-Code (J1750). No entries exist for Proferdex in that time period.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 15<sup>th</sup> day of June, 2006.

  
Michelle L. Butler


# EXHIBIT A

Proposed Class Representative:  
 Pipefitters Local 537 Trust Funds  
 (Class 3)

Name	Date of Admin	Drug of Admin	J Code
not available	4/26/2001	dexamethasone sodium phosphate	J1100
not available	5/3/2001	dexamethasone sodium phosphate	J1100
not available	5/17/2001	dexamethasone sodium phosphate	J1100
not available	2/18/2004	dexamethasone sodium phosphate	J1100
not available	2/18/2004	dexamethasone sodium phosphate	J1100
not available	5/19/2005	dexamethasone sodium phosphate	J1100
not available	8/16/1999	diazepam	J3360
not available	11/13/2002	vancomycin	J3370

# **EXHIBIT B**

Proposed Class Representative:  
Sheet Metal Workers National Health Fund  
(Class 2)

Name	Date of Admin.	Drug or Admin.	J Code
redacted*	4/26/04	dexamethasone acetate	J1094
redacted	5/6/04	dexamethasone acetate	J1094
redacted	7/31/98	dexamethasone sodium phosphate	J1100
redacted	8/24/98	dexamethasone sodium phosphate	J1100
redacted	8/25/98	dexamethasone sodium phosphate	J1100
redacted	8/26/98	dexamethasone sodium phosphate	J1100
redacted	8/27/98	dexamethasone sodium phosphate	J1100
redacted	8/28/98	dexamethasone sodium phosphate	J1100
redacted	9/21/98	dexamethasone sodium phosphate	J1100
redacted	9/22/98	dexamethasone sodium phosphate	J1100
redacted	9/23/98	dexamethasone sodium phosphate	J1100
redacted	9/24/98	dexamethasone sodium phosphate	J1100
redacted	9/25/98	dexamethasone sodium phosphate	J1100
redacted	10/19/98	dexamethasone sodium phosphate	J1100
redacted	10/20/98	dexamethasone sodium phosphate	J1100
redacted	10/21/98	dexamethasone sodium phosphate	J1100
redacted	10/22/98	dexamethasone sodium phosphate	J1100
redacted	10/23/98	dexamethasone sodium phosphate	J1100
redacted	8/9/00	dexamethasone sodium phosphate	J1100
redacted	2/13/01	dexamethasone sodium phosphate	J1100
redacted	2/13/01	dexamethasone sodium phosphate	J1100
	4/10/01	dexamethasone sodium phosphate	J1100

\* Contained in Randle Affidavit.

Proposed Class Representative:  
Sheet Metal Workers National Health Fund  
(Class 2)

Name	Date of Admin.	Date of Admin.	J-Code
redacted	5/1/01	dexamethasone sodium phosphate	J1100
redacted	9/17/01	dexamethasone sodium phosphate	J1100
redacted	9/24/01	dexamethasone sodium phosphate	J1100
redacted	10/1/01	dexamethasone sodium phosphate	J1100
redacted*	10/9/01	dexamethasone sodium phosphate	J1100
redacted	10/15/01	dexamethasone sodium phosphate	J1100
redacted	11/1/01	dexamethasone sodium phosphate	J1100
redacted*	3/8/02	dexamethasone sodium phosphate	J1100
redacted	8/27/02	dexamethasone sodium phosphate	J1100
redacted	2/4/03	dexamethasone sodium phosphate	J1100
redacted	9/10/03	dexamethasone sodium phosphate	J1100
redacted	1/5/04	dexamethasone sodium phosphate	J1100
redacted	1/19/04	dexamethasone sodium phosphate	J1100
redacted	2/2/04	dexamethasone sodium phosphate	J1100
redacted	3/10/04	dexamethasone sodium phosphate	J1100
redacted	3/30/04	dexamethasone sodium phosphate	J1100
redacted	3/31/04	dexamethasone sodium phosphate	J1100
redacted	4/6/04	dexamethasone sodium phosphate	J1100
redacted	4/6/04	dexamethasone sodium phosphate	J1100
redacted	4/13/04	dexamethasone sodium phosphate	J1100
redacted	4/21/04	dexamethasone sodium phosphate	J1100

\* Contained in Randle Affidavit.

Proposed Class Representative:  
Sheet Metal Workers National Health Fund  
(Class 2)

Name	Date of Admin.	Drug of Admin.	J-Code
redacted	5/19/04	dexamethasone sodium phosphate	J1100
redacted	5/26/04	dexamethasone sodium phosphate	J1100
redacted	6/9/04	dexamethasone sodium phosphate	J1100
redacted	6/22/04	dexamethasone sodium phosphate	J1100
redacted	6/24/04	dexamethasone sodium phosphate	J1100
redacted	6/29/04	dexamethasone sodium phosphate	J1100
redacted	8/25/04	dexamethasone sodium phosphate	J1100
redacted	9/1/04	dexamethasone sodium phosphate	J1100
redacted	9/8/04	dexamethasone sodium phosphate	J1100
redacted	9/15/04	dexamethasone sodium phosphate	J1100
redacted	12/16/04	dexamethasone sodium phosphate	J1100
redacted	1/7/05	dexamethasone sodium phosphate	J1100
redacted	1/27/05	dexamethasone sodium phosphate	J1100
redacted	3/29/05	dexamethasone sodium phosphate	J1100
redacted	12/5/01	gentamicin sulfate	J1580
redacted*	1/7/04	gentamicin sulfate	J1580
redacted*	9/12/02	diazepam	J3360
redacted	12/5/01	vancomycin	J3370
redacted	9/12/03	vancomycin	J3370
redacted*	9/19/05	vancomycin	J3370